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North Carolina H1N1 Vaccination Issues Q&A

July 15, 2009

As with all information related to H1N1, this is a very fluid situation. Please keep up to date by frequently visiting the websites listed below.

Who is manufacturing the H1N1 vaccine?

There are currently five pharmaceutical companies working on H1N1 vaccines. They are Novartis, Sanofi Pasteur, CSL, MedImmune and Glaxo Smithkline.

When will the H1N1 vaccine be available?

CDC currently anticipates that the H1N1 vaccine will be available in October 2009. This is subject to change.

How much H1N1 vaccine will be available?

The current vaccine manufacturing plan calls for enough vaccine to vaccinate everyone. The initial release is expected to be between 40 and 160 million doses, followed by weekly shipments between 10 and 30 million doses.

CDC provided the following estimates to NC for planning purposes ONLY. These estimates reflect the amounts based on the 3 scenarios that NC may receive during vaccine distribution. These numbers WILL change based on actual amounts of vaccine produced and distributed.

40M-dose initial bolus	80M-dose initial bolus	160M-dose initial bolus	10M doses per week	20M doses per week	30M doses per week
1,148,907	2,297,814	4,595,627	287,227	574,453	861,680

Will this be an injectable or nasal spray vaccine?

The bulk of the supply will be injectable vaccine. However, Medimmune is also working on a nasal spray version of the vaccine.

How will the doses be packaged?

H1N1 vaccine will be filled/finished in a 5mL vial/10 doses per vial. Approximately 15% of the vaccine may come in pre-filled syringes or nasal sprayers (LAIV) for the pediatric population. Information on vaccine packaging for shipping is not currently available.

How many doses of the H1N1 vaccine will people need to receive?

This vaccine is expected to be a two dose series, with the doses given about 1 month apart.

Will this vaccine also cover seasonal influenza?

No, people will also need to have a regular seasonal flu vaccination.

Who will distribute this vaccine?

CDC is still trying to determine a distribution plan. There are two scenarios currently under consideration. The first is distribution from the manufacturer to designated "ship-to" points. In NC those "ship-to" points would likely be local health departments. The second is distribution through McKesson to public and private providers, similar to how UCVDP (childhood) vaccines are currently



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distributed. Once a decision is made on the method of distribution, NC will be able to provide counties with better estimates of the amounts of vaccine that may be received at the health departments and with whom that vaccine will need to be shared.

Who will be given priority to receive this vaccine?

CDC has not yet decided if the vaccine will be given by priority groups, and if so, the makeup of the groups. ACIP is having a special meeting at CDC on July 29, 2009 to discuss H1N1 issues including priority groups. CDC indicated on 7/13/09 that states will not have to report doses administered by priority group, but instead by age group of the recipient.

Where will people go to get this vaccine?

It is anticipated that local health departments will have the vaccine as well as hospitals, private providers and other health care venues. However, CDC has not yet issued final guidance on this issue. Because H1N1 flu has so far been seen more in younger people, schools may play a significant role in administration of this vaccine. As soon as more concrete information is available from CDC on this issue, local health departments will be notified.

Will providers be able to order this vaccine themselves from the manufacturer or pharmaceutical distributors?

No, this vaccine is being manufactured for the federal government, and its distribution will be determined by the CDC. It will not be available for private purchase.

If providers are given a supply of vaccine to administer, will they be able to charge for the vaccine?

CDC has not resolved this issue. It is likely that providers will not be able to charge for the vaccine itself because it is being paid for by the federal government. However, providers may be able to charge an administration fee. (This would be similar to how we currently handle state supplied vaccines.)

In addition, The Association of Health Plans collected information from their members about how to cover the reimbursement of the H1N1 vaccine. Overall, the information was positive with a sense that plans want to cover this, even if the vaccine is issued under an Emergency Use Authorization (EUA).

We will update you as we learn more about this issue.

How will doses administered be tracked?

The tentative plan is that providers who use NCIR will enter doses into the system. Providers who do not use NCIR or those who are not able to utilize the system at their clinic sites will complete paper documentation which will be entered into NCIR by data entry staff hired specifically for this purpose. PLEASE NOTE: CDC requires that each dose of the vaccine be accounted for and tracked. Because this is a two dose series, there must be adequate documentation of when the doses are given. The Immunization Branch is required to report information on doses administered in NC to CDC on a weekly basis.

How will providers report adverse vaccination events?

The current plan is for adverse reactions related to the H1N1 vaccine to be reported through the Vaccine Adverse Event Reporting System (VAERS), as is done for other vaccines. VAERS reports can be filed on-line at <https://secure.vaers.org/VaersDataEntryintro.htm>, by fax to 1-877-721-0366 or by mail. The VAERS form is online at http://vaers.hhs.gov/pdf/vaers_form.pdf.

Where can providers/public get up to date information about the vaccine?

www.cdc.gov/h1n1flu is the most up to date resource for general information about H1N1 influenza, disease rates and management and vaccine development.

North Carolina specific H1N1 information can be found at www.epi.state.nc.us/epi/gcdc/H1N1flu.html